

Remarks

Claims 1-20 are pending in the instant application. Claims 10-13 and 16-19 have been deemed to be withdrawn. Applicants have hereinabove cancelled claims 4 and 15 without disclaimer or prejudice to their right to pursue the subject matter of these claims in a future application. In addition, applicants have hereinabove amended claims 1, 5, and 14. Support for the amendments to the claims may be found, *inter alia*, in the subject specification as follows: claim 1: Example 1 and claim 14. The remaining changes to the claims merely introduce minor grammatical and format changes. This Amendment does not involve any issue of new matter. Therefore, entry of this Amendment is respectfully requested such that claims 1-3, 5-9, 14 and 20 will be pending and under examination.

Claim Rejection Under 35 U.S.C. §102(b)

The Examiner rejected claim 1-8 and 15 under 35 U.S.C. §102(b) as allegedly being anticipated by Schwartz et al. (*J. Clin. Pharmacol.*, 2001).

In response, applicants respectfully traverse. Nevertheless, applicants without conceding the correctness of the Examiner's position and to expedite prosecution of the subject application have hereinabove amended claim 1 such that it no longer recites step (B).

The present invention is directed to a therapeutic regimen whereby the use of a cyclooxygenase-2 selective inhibitor, such as rofecoxib, in combination with a disease modifying anti-rheumatic drug (DMARD), such as methotrexate, leads to a shorter-term use of the DMARD and/or a reduction in the dose of the prescribed DMARD (see page 1 "Background of the Invention"; page 5, paragraph defining "combination dosage regimen"; and Example 1). Claim 1, as amended, recites: "A DMARD sparing method for treating a chronic inflammatory disease or condition in a human patient in need thereof, comprising administering to the patient a therapeutically effective amount of a DMARD in accordance with a DMARD dosage regimen for a period of time, and thereafter: co-administering to the patient a therapeutically effective amount of a DMARD and a cyclooxygenase-2 selective inhibitor in accordance with a combination dosage regimen, *whereby the total exposure to the DMARD is reduced*" (emphasis added).

In the specification, applicants define the term “combination dosage regimen” to mean any amount of the cyclooxygenase-2 selective inhibitor and DMARD that when co-administered, are effective to treat the chronic inflammatory disease or condition; *provided, however, that total exposure to the DMARD is reduced* (see page 6 of the subject specification).

Applicants note that Schwartz et al. does not describe reducing the patient's total exposure to the DMARD, i.e. methotrexate. Schwartz et al. state in the "Study Design" section on page 1121 that "[d]uring the entire 3-week study, eligible patients maintained their regularly prescribed weekly dose of oral methotrexate." Therefore, although the dose of the DMARD (methotrexate) given to each patient ranged from 7.5 mg - 20 mg per week, once a patient was prescribed a certain dosage of methotrexate, that amount remained constant throughout the study, i.e. the amount of the DMARD was not reduced. Therefore, Schwartz et al. does not recite each and every element of claim 1, or claims 2, 3, 5-9, 14 and 20 which depend therefrom. Since Schwartz et al. does not recite each and every element of claim 1, or claims 2, 3, 5-9, 14 and 20, it does not anticipate applicants' claimed invention as set forth therein.

In light of the above remarks, applicants maintain that claim 1, or claims 2, 3, 5-9, 14 and 20 satisfy the requirements of 35 U.S.C. §102(b). Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Claim Rejection Under 35 U.S.C. §103(a)

The Examiner rejected claims 9, 14, and 20 under 35 U.S.C. §103(a) as allegedly being unpatentable over Schwartz et al. (*J. Clin. Pharmacol.*, 2001) as applied to claim 1-8 and 15 above, and further in view of Merck & Co, Inc. (1989) and *Physicians' Desk Reference*.

In response, applicants respectfully traverse. Nevertheless, applicants without conceding the correctness of the Examiner's position and to expedite prosecution of the subject application have hereinabove amended claim 1, from which claims 9, 14 and 20 depend, such that it no longer recites step (B). As discussed above Schwartz et al. does not describe reducing the amount of DMARD (methotrexate) administered to the patient as recited in amended claim 1. Therefore, since Schwartz et al. does not recite each and every element of claim 1, it does not anticipate applicants' invention set forth in claims 9, 14 and 20. Since Schwartz et al. is not prior art against claims 9, 14 and 20, applicants' claimed invention cannot be obvious in light of its teachings.

Likewise, applicants note that neither the Vioxx Information Pamphlet (Merck & Co, Inc.) nor the Physicians' Desk Reference remedy the deficiency of Schwartz et al. Neither reference describes reducing the amount of DMARD (methotrexate) administered to the patient. Therefore, neither reference is prior art against claims 9, 14 and 20. Since these references are not prior art against claims 9, 14 and 20, applicants' claimed invention cannot be obvious in light of their teachings.

In light of the above remarks, applicants maintain that claims 9, 14 and 20 satisfy the requirements of 35 U.S.C. §103(a). Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Summary

For the reasons set forth hereinabove, applicants respectfully request that the Examiner reconsider and withdraw the various grounds of rejection and earnestly solicit allowance of the pending claims.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone her at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 13-2755 referencing docket no. 21411P.

Respectfully submitted,

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Date: September 9, 2009